

## **REMARKS**

Reconsideration of this application is respectfully requested in view of the foregoing amendment and the following remarks.

Claims 1-19 were pending in this application. In this Amendment, Applicants have amended claims 8-19 and canceled claims 1, 2, and 5-7. Claims 8-11 and 13-19 were amended as suggested by the Examiner merely to address formalities. Claim 12 was amended to more clearly recite the subject matter of the present invention without the intention of narrowing or otherwise affecting the scope of the claim. Accordingly, claims 3, 4, and 8-19 will be pending upon entry of this Amendment.

In the Office Action mailed March 16, 2006, claims 5-11 and 13-19 were objected to for informalities. Claims 1-11 were rejected under 35 U.S.C. § 103(a) based on U.S. Patent No. 6,613,064 to Rutynowski et al. ("Rutynowski") in view of U.S. Patent No. 6,558,402 to Chelak et al. ("Chelak"). Claims 12-19 were rejected under 35 U.S.C. § 103(a) based on Rutynowski. To the extent these rejections might still be applied to claims presently pending in this application, Applicants respectfully traverse the rejections.

Claims 1, 2, and 5-7 have been canceled. Accordingly, the rejection of those claims is moot.

Claims 8-11 and 13-19 were amended as suggested by the Examiner and, accordingly, Applicant respectfully requests withdrawal of the objections.

**35 U.S.C. § 103(a): Claims 3, 4, and 8-19**

Independent claims 3 and 4 each recite a push element comprising “a turnably mounted therein puncturing force adjusting member, which comprises ... inwardly directed...members pressing the piston in operation.” Claim 3 recites that the inwardly directed members are oblique half-ring members and claim 4 recites that the inwardly directed members are stair shaped members. The Examiner has not identified any portion of Chelak that discloses, teaches, or suggests these features, and instead relies on one or more of design choice, rearrangement of parts, or reversal of parts rationales based on the Rutynowski reference. Applicant respectfully submits that the rejection is improper as the Examiner has failed to present a *prima facie* showing of obviousness by inappropriately relying on legal precedent to fill gaps in the references. It is respectfully noted that Chelak was only cited by the Examiner to show features related to claims that are no longer pending.

In the Office Action, the Examiner acknowledged that Rutynowski does not disclose a force adjusting member that extends from the push element and presses the piston. For this element, the Examiner stated that it would have been obvious as a matter of design choice to modify Rutynowski by shifting the location of the depth adjusting member so that it extends from the push element and presses against the top portion of the piston. Applicant respectfully disagrees. The Examiner’s reliance on case law in this particular situation is without merit in view of, *inter alia*, the critical features and enhanced performance of the device as claimed, which includes force adjusting, rather than depth adjusting, capabilities. Applicant respectfully

directs attention to MPEP § 2144.04, which pertains to the use of case law and “matters of routine skill in the art,” and which states (with emphasis added):

[I]f the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court...**If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection.**

The facts of the present case are far from similar to those in either of the cases cited by the Examiner. Further, the features as claimed in the present invention indeed have criticality, as has been explained by the Applicant in the previous response and as further explained below such that it would be improper to rely solely on case law as the rationale to support an obviousness rejection.

In *In re Japikse*, 181 F.2d 1019 (CCPA 1950), claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device (see MPEP § 2144.04.VI.C). Clearly, the present invention is in no way similar to the inconsequential placement of a machine switch. In the *Japikse* case, the switch had essentially the same function no matter where it was located and the essential parts with which it interacted were the same in either case. In the present case, on the other hand, the force adjusting member has a completely different purpose (*i.e.*, needle impact force adjustment rather than needle depth adjustment) and carries out this purpose by interacting with entirely different parts and in a different manner than the depth adjusting member of Rutynowski. Further, the claimed force adjusting member in the present invention modifies the operation of the device by

providing the ability to adjust the force of impact of the needle depending on the patient's skin type or other concerns, and may therefore have the advantage of reducing painful effects of the puncturing device. That is, for patients with thin, delicate skin, the force of impact may be reduced so that the patient feels less pain at the *same depth* of penetration. For patients with thicker skin, the force of impact of the needle may be increased so as to ensure an adequate depth of penetration. These adjustments cannot be made in the device of Rutynowski.

In particular, the present invention enables regulation of the puncturing energy in addition to or in lieu of puncture depth regulation. That is, at every set puncturing depth (or in cases where the depth is not limited), the force of the needle puncturing a patient's skin can be adjusted to meet specific patient needs by adjusting the tension in the drive spring at the moment of activation of the piston. This is accomplished by an adjustable member extending from a face of a push element such that the distance between the face and the piston may be reduced or enlarged. Since the drive spring extends between the push element and the piston, the energy stored in the drive spring is adjusted by this change in distance. The energy with which the puncturing tip enters a patient's skin is thereby regulated and may be changed to accommodate specific needs of the patient. The device of Rutynowski cannot provide this level of customization. Further, the parts of Rutynowski cannot simply be rearranged to arrive at the claimed invention. Entirely different structure, as well as function, having significant advantages over Rutynowski are embodied in the present invention as claimed.

In the device of Rutynowski, for example, the drive spring must be configured at the outset to provide a puncture force to accommodate every patient, thick- or thin-skinned.

Therefore, especially for patients with thin skin, there is excess energy stored in the drive spring upon impact that must be absorbed by the penetration depth limiting device and, in turn, by the patient. This absorption of energy leads to increased and unnecessary pain. The present invention aims to solve this problem by allowing for adjustment of the puncturing force by altering the energy stored in the drive spring at the moment of activation of the piston.

As can be seen, a puncturing device that only limits depth of penetration without regard to the force of impact runs the risk of causing unnecessary pain in patients with thin skin and insufficient blood-taking in patients with thick skin. The force adjusting capability provides an additional layer of adaptation in meeting specific patient needs and therefore represents a significant modification over the prior art. Since a modification exists and this case is not a mere rearrangement of inconsequential parts as in *Japikse*, the obviousness rejection is improper and, accordingly, Applicant respectfully requests its withdrawal.

The Examiner also cites *In re Gazda*, 219 F.2d 449 (CCPA 1955), as legal precedent for the proposition that a mere reversal of parts of a prior art device is not patentable. Firstly, Applicant is unclear as to which parts of Rutynowski the Examiner is alleging have been reversed. In *Gazda*, the prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious expedient (see MPEP § 2144.04.VI.A). Applicant is unclear as to the relevance of the facts of the *Gazda* case, let alone how they may be “sufficiently similar” to the facts in the present case, as is required by the MPEP. There is no reversal of parts in the present invention as compared to the Rutynowski

device. A new and different element (*i.e.*, a turnably mounted puncturing force adjusting member that presses the piston in operation) has been implemented that has entirely different structural features, functions, and effects. For at least these reasons, Applicant respectfully submits that *Gazda* is inapplicable and, accordingly, withdrawal of the rejection is respectfully requested.

Claims 8-11 are patentable over Rutynowski in view of Chelak at least by virtue of their dependency from claims 3 and 4 and for the additional features recited therein.

In the rejection of claim 12 under 35 U.S.C. § 103(a) based solely on Rutynowski, the Examiner used identical rationale to that used in the rejection of claims 3 and 4. The Examiner similarly acknowledges the missing elements in the disclosure of Rutynowski and relies on one or more of design choice, rearrangement of parts, or reversal of parts rationales to fill the gaps in the reference. For at least the same reasons provided above, Applicant respectfully submits that the Examiner's reliance on legal precedent in this case is wholly inappropriate and, accordingly, that claim 12 is likewise patentable over Rutynowski.

Claims 13-19 are patentable over Rutynowski at least by virtue of their dependency from claim 12 and for the additional features recited therein.

In the "Response to Arguments" section of the Office Action of September 11, 2006, the Examiner seems to refer to an "intended use" line of reasoning to support the rejection of the claims. Applicant respectfully submits that this rationale is also improper. Firstly, the depth adjusting member of Rutynowski **does not** comprise each and every structural element of the claimed force adjusting member, as alleged by the Examiner. For example, the depth adjusting

member of Rutynowski does not meet the structural limitation of “wherein the push element comprises a turnably mounted therein puncturing force adjusting member, which comprises an inwardly directed pair of oblique half-ring members pressing the piston in operation,” as claimed in claim 3 or “wherein the push element comprises a turnably mounted therein puncturing force adjusting member, which comprises inwardly directed stair shaped members pressing the piston in operation,” as claimed in claim 4.

With respect to claim 12, Rutynowski does not meet the structural limitations reciting that the force adjusting member is “configured to press the piston,” or “configured to change the distance between a face of the adjustable push element and the piston at the position at which the member presses the piston.” Also with respect to claim 12, the drive spring of Rutynowski is not compressed “until the member presses the piston sufficiently enough to break the wing.”

All of these features recited in claims 3, 4, and 12 embody structural limitations that are not met by the device of Rutynowski. In order to fill gaps between the prior art and the claims where the only gap is a functional limitation, it is elementary that the Examiner must first make a showing that the prior art meets all of the structural claim limitations. In view of the above-listed structural claim features that have not been met and in view of the inappropriate use of legal precedent asserted by the Examiner, this has not been done. Accordingly, the Examiner cannot rely on “intended use” or “functional limitation” rationale to fill the gaps. See MPEP § 2173.05(g).

The Examiner’s second point in the “Response to Arguments” section appears to be an attempt to further support the intended use rationale. Whether or not a “depth-adjusting

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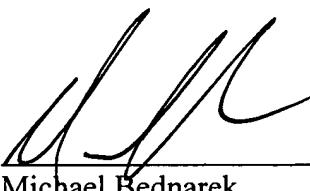
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member" is equivalent to a "force-adjusting member" in the abstract has little bearing on whether Rutynowski meets the structural recitations in the claims (although, incidentally, they are not equivalent; if the Examiner has any doubts about this fact, Applicant would be glad to supply mathematical data to support this contention). The force adjusting member of the present invention, including all of the features claimed in claim 12, has distinct advantages over the purely depth-adjusting device of Rutynowski, as discussed above. For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 3, 4, and 8-19.

In view of the foregoing, all of the claims in this case are believed to be in condition for allowance. Should the Examiner have any questions or determine that any further action is desirable to place this application in even better condition for issue, the Examiner is encouraged to telephone Applicants' undersigned representative at the number listed below.

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